PTO/SB/08a (07-09)

Approved for use through 07/31/2012. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

| Sub   | estitute for form 1449/PTO |         |              | Complete if Known      |                  |  |
|-------|----------------------------|---------|--------------|------------------------|------------------|--|
|       |                            |         |              | Application Number     | 10/587,512       |  |
| IN    | <b>IFORMATION</b>          | I DI    | SCLOSURE     | Filing Date            | November 8, 2007 |  |
| S     | TATEMENT E                 | 3Y /    | APPLICANT    | First Named Inventor   | Justin Hanes     |  |
|       |                            |         |              | Art Unit               | 1632             |  |
|       | (Use as many she           | eets as | s necessary) | Examiner Name          | M. K. Sgagias    |  |
| Sheet | Sheet 1 of 4               |         |              | Attorney Docket Number | JHUC-P01-021     |  |

|                       |              |  | U.S. PA                        | TENT DOCUMENTS                                     |   |
|-----------------------|--------------|--|--------------------------------|--|---|
| Examiner<br>Initials* | Cite<br>No.1 | Document Number  Number-Kind Code <sup>2</sup> ( if known) | Publication Date<br>MM-DD-YYYY | Name of Patentee or<br>Applicant of Cited Document | Pages, Columns, Lines, Where<br>Relevant Passages or Relevant<br>Figures Appear |
| M.S./                 | AB*          | US-7,163,697   | 01-16-2007                     | Hanes et al.                                       |   |
|                       | AC*          | US-5,985,309   | 11-16-1999                     | Edwards et al.                                     |   |
|                       | AD*          | US-5,916,596   | 06-29-1999                     | Desai et al.                                       |   |
|                       | AE*          | US-5,718,921   | 02-17-1998                     | Mathiowitz et al.                                  |   |
|                       | AF*          | US-5,578,325   | 11-26-1996                     | Domb et al.  |   |
|                       | AG*          | US-4,999,417   | 03-12-1991                     | Domb   |   |
|                       | AH*          | US-4,906,474   | 03-06-1990                     | Langer et al.                                      |   |
|                       | Al*          | US-4,868,274   | 09-19-1989                     | Gupta et al.                                       |   |
|                       | AJ*          | US-4,792,598   | 12-20-1988                     | Ziegast  |   |
|                       | AK*          | US-4,789,724   | 12-06-1988                     | Domb et al.  |   |
|                       | AL*          | US-4,757,128   | 07-12-1988                     | Domb et al.  |   |
|                       | AM*          | US-20080166414   | 07-10-2008                     | Hanes et al.                                       |   |
|                       | AN*          | US-20060083781   | 04-20-2006                     | Shastri et al.                                     |   |
|                       | AO*          | US-20050101676   | 05-12-2005                     | Fahl et al.  |   |
|                       | AP*          | US-20040258763   | 12-23-2004                     | Bell   |   |
|                       | AQ*          | US-12/310,751  | Filed 3/6/09                   | Hanes et al.                                       |   |
|                       |              |  |                                |  |   |
|                       |              |  |                                |  |   |
|                       |              |  |                                |  |   |

|           |      | FOREI   | GN PATENT          | DOCUMENTS                           |   |  |
|-----------|------|---|--------------------|-------------------------------------|---|--|
| Examiner  | Cite | Foreign Patent Document   | Publication        | Name of Patentee or                 | Pages, Columns, Lines,                                |  |
| Initials* | No.1 | Country Code <sup>3</sup> -Number <sup>4</sup> -Kind Code <sup>5</sup> (if known) | Date<br>MM-DD-YYYY | Applicant of Cited Document         | Where Relevant Passages<br>Or Relevant Figures Appear |  |
|           | ВА   | EP-0 692 510  | 12-22-2004         | Mass. Inst. of Technology           |   |  |
|           | BB   | WO-02/053189  | 07-11-2002         | Timmerman, B.                       |   |  |
|           | ВС   | WO-2005/072710  | 08-11-2005         | Johns Hopkins University            |   |  |
|           | BD   | WO-2007/133808  | 11-22-2007         | Liquidia Technologies, Inc.         |   |  |
|           | BE   | WO-98/29097   | 07-09-1998         | Quadrant Holdings<br>Cambridge Ltd. |   |  |
|           | BF   | WO-99/01498   | 01-14-1999         | Danbiosyst UK Limited               |   |  |
|           | BG   | WO-95/22318   | 08-24-1995         | Vernnon et al.                      |   |  |
|           | вн   | WO-95/03356   | 02-02-1995         | Mass. Inst. of Technology           |   |  |
|           |      | ·   | •                  | ·                                   | VE 14 0 10 04 0                                       |  |

| Examiner /Mannalene Snanias/ Date 00/10/2010 |  |
|--|--|
| Signature Considered Considered              |  |
| Odrisidered                                  |  |

<sup>\*</sup>EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. \* CITE NO.: Those application(s) which are marked with an single asterisk (\*) next to the Cite No. are not supplied (under 37 CFR 1.98(a)(2)(iii)) because that application was filed after June 30, 2003 or is available in the IFW. ¹ Applicant's unique citation designation number (optional). ² See Kinds Codes of USPTO Patent Documents at <a href="https://www.uspto.gov">www.uspto.gov</a> or MPEP 90.104. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japaneses patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

Receipt date: 12/15/2009 10587512 - GAU: 1632

PTO/SB/08b (07-09)
Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

| Sub   | ostitute for form 1449/PTO |         |              | Complete if Known      |                  |  |
|-------|----------------------------|---------|--------------|------------------------|------------------|--|
|       |                            |         |              | Application Number     | 10/587,512       |  |
| l IN  | <b>IFORMATION</b>          | 1 DI    | SCLOSURE     | Filing Date            | November 8, 2007 |  |
| l s   | TATEMENT E                 | 3Y /    | APPLICANT    | First Named Inventor   | Justin Hanes     |  |
|       |                            |         |              | Art Unit               | 1632             |  |
|       | (Use as many sh            | eets as | s necessary) | Examiner Name          | M. K. Sgagias    |  |
| Sheet | 2                          | of      | 4            | Attorney Docket Number | JHUC-P01-021     |  |

|                      |                          | NON PATENT LITERATURE DOCUMENTS   |                |
|----------------------|--------------------------|---|----------------|
| Examiner<br>Initials | Cite<br>No. <sup>1</sup> | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. | T <sup>2</sup> |
| /M.S./               | СН                       | Albertsson et al., Characterization and Degradation fo Aliphatic Polyanhydrides. British Polyner J. 23, 205-12 (1990)   |                |
|                      | СІ                       | Brorson et al., Mutational Analysis of Avidity and Fine Specificity of Anti-Levan Antibodies. J. Immunol. Vole. 163, pages 6694-6701 (1999)   |                |
|                      | CJ                       | Brummell et al., Probing the combining site of an anti-carbohydrate antibody by saturation-mutagenesis: role of the heavy-chain CDR3 residues. Biochemistry Vol. 32 pages 1180-1187 (1993)  |                |
|                      | СК                       | Burks et al., In vitro scanning saturation mutagenesis of an antibody binding pocket. PNAS Vol. 94. pages 412-417 (1997)  |                |
|                      | CL                       | Chan, et al. Phase behavior and miscibility in blends of poly(sebacic anhydride)/ poly(ethylene glycol). Biomaterials 23, 2353-58 (2002)  |                |
|                      | СМ                       | Colman, Effects of amino acid sequence changes on antibody-antigen interactions. Research in Immunol. Vol. 145 pages 33-36 (1994)   |                |
|                      | CN                       | Dawson et al., Enhanced Viscoelasticity of Human Cystic Fibrotic Sputum Correlates with Increasing Microheterogeneity in Particle Transport. The Journal of Biological Chemistry. Vol. 278 pages 50393-50401 (2003)   |                |
|                      | СО                       | Dufner et al., Harnessing phage and ribosome display for antibody optimisation. Trends Biotechnol. Vol. 24, No. 11, pages 523-529 (2006)  |                |
|                      | СР                       | Ehrhardt et al., Drug Absorption by the Respiratory Mucosa: Cell Culture Models and Participate Drug Carriers. Journal of Aerosol Medicine. Vol. 15, No. 2. pages 131-139 (2002)  |                |

|           | <u> </u>            |            | <u> </u>   |
|-----------|---------------------|------------|------------|
| Examiner  | /Maggalene Sgaglas/ | Date       | 05/18/2010 |
| Signature | ,                   | Considered | 00.10.110  |

<sup>\*</sup>EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Applicant's unique citation designation number (optional). Applicant is to place a check mark here if English language Translation is attached.

Receipt date: 12/15/2009 10587512 - GAU: 1632

PTO/SB/08b (07-09)
Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

| Sub   | ostitute for form 1449/PTO |         |              | Complete if Known      |                  |  |
|-------|----------------------------|---------|--------------|------------------------|------------------|--|
|       |                            |         |              | Application Number     | 10/587,512       |  |
| l IN  | <b>NFORMATION</b>          | 1 DI    | SCLOSURE     | Filing Date            | November 8, 2007 |  |
| l s   | TATEMENT E                 | 3Y /    | APPLICANT    | First Named Inventor   | Justin Hanes     |  |
|       |                            |         |              | Art Unit               | 1632             |  |
|       | (Use as many sh            | eets as | s necessary) | Examiner Name          | M. K. Sgagias    |  |
| Sheet | 3                          | of      | 4            | Attorney Docket Number | JHUC-P01-021     |  |

|                      |              | NON PATENT LITERATURE DOCUMENTS   |            |
|----------------------|--------------|---|------------|
| Examiner<br>Initials | Cite<br>No.1 | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. | <b>T</b> 2 |
| /M.S                 | ¢Ω           | Jang et al., The structural basis for DNA binding by an anti-DNA autoantibody. Molec. Immunol. Vol. 35, pages 1207-1217 (1998)  |            |
|                      | CR           | Jiang et al. Preparation, characterization and degradation characteristics of polyanhydrides containing poly(ethylene gylcol). Polym Int. 48, 47-52 (1999)  |            |
|                      | cs           | Jiang et al., Pulsatile protein release from a laminated device comprising of polyanhydrides and pH-sensitive complexes. <i>Int. J. Pharmaceutics</i> 194, 51-60 (2000)   |            |
|                      | СТ           | Kobayashi et al., Tryptophan H33 plays an important role in pyrimidine (6-4) pyrimidone photoproduct binding by a high-affinity antibody. Protein Engineering Vol. 12, pages 879-884 (1999)   |            |
|                      | CU           | Lai et al., Rapid transport of large polymeric nanoparticles in fresh undiluted human mucus. PNAS Vol. 104, No. 5 pages 1482-1487 (2007)  |            |
|                      | cv           | Lipman et al., Monoclonal Versus Polyclonal Antibodies: Distinguishing Characteristics, Applications, and Information Resources. ILAR Journal Vol. 46, No. 3. pages 258-268 (2005)  |            |
|                      | cw           | Liyan, Q. et al. Compatibility and degradation of new polyphosphazene/polyanhydride blend. Gaofenzi Xuebao 5, 660-664 (2001), Chemical Abstracts Service, Accession No. 2001:817417.  |            |
|                      | сх           | Peracchia, M. T. et al. PRG-coated nanospheres from amphiphilic diblock and multiblock copolymers: Investigation of their drug encapsulation and release characteristics. <i>J. Controlled Release</i> 46, 223-231 (1997).                                      |            |
|                      | CY           | Qiu, L. Y. & Zhu, K. J. Design of a core-shelled polymer cylinder for potential programmable drug delivery. <i>Int. J. Pharm.</i> 219, 151-160 (2001).  |            |

| Examiner  | /iviaqoaierie 5qaqias/ | Date       | 05/18/2010 |
|-----------|------------------------|------------|------------|
| Signature | -0-0-0-0               | Considered | USITUIEUTU |

<sup>\*</sup>EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>&</sup>lt;sup>1</sup>Applicant's unique citation designation number (optional). <sup>2</sup>Applicant is to place a check mark here if English language Translation is attached.

Receipt date: 12/15/2009 10587512 - GAU: 1632

PTO/SB/08b (07-09)
Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

| Sub   | ostitute for form 1449/PTO |         |              | Complete if Known      |                  |  |
|-------|----------------------------|---------|--------------|------------------------|------------------|--|
|       |                            |         |              | Application Number     | 10/587,512       |  |
| l IN  | <b>IFORMATION</b>          | I DI    | SCLOSURE     | Filing Date            | November 8, 2007 |  |
| l s   | TATEMENT E                 | 3Y /    | APPLICANT    | First Named Inventor   | Justin Hanes     |  |
|       |                            |         |              | Art Unit               | 1632             |  |
|       | (Use as many she           | eets as | s necessary) | Examiner Name          | M. K. Sgagias    |  |
| Sheet | 4                          | of      | 4            | Attorney Docket Number | JHUC-P01-021     |  |

|                      |              | NON PATENT LITERATURE DOCUMENTS   |    |
|----------------------|--------------|---|----|
| Examiner<br>Initials | Cite<br>No.1 | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. | T2 |
| /M.S                 | ·cz          | Rolland et al., Direct Fabrication and Harvesting of Monodisperse, Shape-Specific Nanobiomaterials. J. AM. Chem. Soc. Vol. 127 pages 10096-10100 (2005)   |    |
|                      | CA1          | Shuai, X. et al. Synthesis and characterization of several degradable aliphatic polyanhydrides. J. Beijing Inst. Tech. 5, 130-136 (1996), Chemical Abstract Service, Accession No. 1997:364424.   |    |
|                      | CB1          | Wu, C. et al. Novel Nanoparticles Formed via Self-Assembly of Poly(ethylene glycol- <i>b</i> -sebacic anhydride) and Their Degradation in Water. <i>Macromolecules</i> 33, 9040-9043 (2000).  |    |
|                      |              |   |    |
|                      |              |   |    |
|                      |              |   |    |

| Examiner  | /Mandalene Sqaqias/   | Date       | 05/10/0010 |
|-----------|-----------------------|------------|------------|
| Signature | /ividyudiene Syayids/ | Considered | 03/10/2010 |

<sup>\*</sup>EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Applicant's unique citation designation number (optional). Applicant is to place a check mark here if English language Translation is attached.